

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

ANNE WEGMANN,)	
)	
Plaintiff,)	
)	
v.)	No. 4:20-CV-00704 JAR
)	
ETHICON, INC., et al.,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon”)'s Motion for Summary Judgment (Doc. No. 39) and Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D. (Doc. No. 41).¹ The motions are fully briefed and ready for disposition. For the following reasons, the motions will be granted in part and denied in part.

I. Procedural history

This matter was recently transferred to this Court from multi-district litigation (“MDL”) in the United States District Court for the Southern District of West Virginia. In re Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation, No. 2:12-md-2327 (S.D. W.Va.). The MDL involves claims of harm resulting from implantation of various polypropylene-based mesh products, including tension-free vaginal tape (“TVT”).

¹ Plaintiff has also filed a motion to exclude the opinions and testimony of one of Ethicon's expert witnesses, Charles Butrick, M.D., and a motion to strike Ethicon's experts that exceed the five-expert limit set by Pretrial Order 328 and to limit Ethicon's employees from offering expert opinions. (Doc. Nos. 43, 69). The Court will address those motions separately.

United States District Judge Joseph Goodwin presided over the MDL, which began in 2012. Numerous cases were filed directly in the Southern District of West Virginia, and many were transferred from other jurisdictions. On August 22, 2012, Judge Goodwin entered Pretrial Order 12, which included a plan for streamlining the pleading process. A 63-page First Amended Master Long Form Complaint was filed, which was described as an “administrative device to set forth potential claims individual Plaintiffs may assert against Defendants” in the litigation. (MDL Doc. No. 238). Also filed was an Amended Short Form Complaint, which served as a template for individual plaintiffs to set out their individual allegations and indicate which counts of the Master Complaint they intended to assert against one or more pelvic mesh producers. (*Id.*, Doc. No. 263).

Plaintiff Anne Wegmann filed her Short-Form Complaint on November 10, 2014, alleging that she had been implanted with Ethicon’s TVT and wished to proceed against Ethicon on all counts raised in the Master Complaint (with the exception of a claim for loss of consortium) as follows:

Count I – Negligence
Count II – Strict Liability – Manufacturing Defect
Count III – Strict Liability – Failure to Warn
Count IV – Strict Liability – Defective Product
Count V – Strict Liability – Design Defect
Count VI – Common Law Fraud
Count VII – Fraudulent Concealment
Count VIII – Constructive Fraud
Count IX – Negligent Misrepresentation
Count X – Negligent Infliction of Emotional Distress
Count XI – Breach of Express Warranty
Count XII – Breach of Implied Warranty
Count XIII – Violation of Consumer Protection Laws
Count XIV – Gross Negligence
Count XV – Unjust Enrichment
Count XVII – Punitive Damages

Count XVIII – Discovery Rule and Tolling

(Doc. No. 1).

Plaintiff's case was placed in "Wave 11" of the MDL. The MDL court entered Pretrial Order 328 on February 4, 2019, which included deadlines for completing discovery and filing dispositive and Daubert motions. (Doc. No. 14). Discovery closed in August 2019 and dispositive and Daubert motions were due shortly thereafter pursuant to the Order. The parties were instructed to file dispositive and Daubert motions (with the exception of Daubert motions regarding general causation) in the applicable member cases – not in the Ethicon MDL. In August 2019, Ethicon filed a motion for summary judgment (Doc. No. 39) and both sides filed Daubert motions (Doc. Nos. 41, 43). These motions were pending when Judge Goodwin transferred Plaintiff's case to this Court in May 2020, noting that discovery was complete and that the parties have had time to file dispositive and Daubert motions. He recommended the case be set for trial without reopening discovery, as doing so would "result in unjust delay." (Doc. No. 54).

The Court held a telephonic status conference with the parties on June 18, 2020. Thereafter, the parties submitted an agreed upon schedule for completing any remaining depositions and their available dates for trial. (Doc. No. 86). The Court entered a Case Management Order on June 25, 2018, ordering the parties to complete all remaining discovery, specifically depositions of Plaintiff's friends and/or family members, no later than January 5, 2021, and setting the case for trial on April 5, 2021. (Doc. No. 87).

II. Factual background²

² The facts are taken from Ethicon's Statement of Undisputed Facts (Doc. No. 40 at 2-4) and Plaintiff's Statement of Material Facts (Doc. No. 45 at 4-9).

On May 14, 2003, Plaintiff underwent implantation of Ethicon's TTV Retropubic Support System for treatment of stress urinary incontinence ("SUI"). The surgery was performed by Dr. Robert Feit in St. Louis, Missouri. Dr. Feit testified he was aware of the risks associated with TTV prior to performing Plaintiff's surgery in 2003, including the risks of infection (including urinary tract infections ("UTIs")) and other urinary problems such as frequency, urgency, dysuria, retention and obstruction. (Deposition Transcript of Dr. Robert Feit ("Feit Depo."), Doc. No. 45-3 at 22:7-25; 70:13-18). He believed that despite the potential risks, TTV was the best option at the time for treating Plaintiff's SUI. (Id. at 49:11-13). Dr. Feit also testified that he continued to stand by his decision to select TTV for Plaintiff and that TTV was a safe and effective treatment. (Id. at 32:22-33:5; 48:4-7; 49:7-13). Dr. Feit had not, however, seen Plaintiff as a patient since May 2014 and had no knowledge of her current medical condition. (Id. at 44:9-12; 45:24-46:1).

Dr. Feit further testified that although he had read the warnings included in the patient brochure, he did not rely on the patient brochure or TTV Instructions for Use ("IFU") to inform himself of the risks associated with TTV. Rather, he relied on Ethicon for accurate and complete information on the risks, benefits and efficacy of the device. (Id. at 58:7-24, 59:3-9, 19-21; 60:19-23; 70:7-12). Among the types of information Dr. Feit considered important to know was (i) whether the TTV exhibited an increased risk of erosion, extrusion, and contraction (id. at 66:8-14; 76:25-77:17); (ii) whether the TTV mesh is brittle, causing particle loss (id. at 79:1-22); (iii) whether the TTV could curl and rope, increasing the potential for retention (id. at 81:23-82:13); and (iv) whether the TTV causes chronic local irritation at the wound site and a chronic foreign body response (id. at 84:15-25). In addition, Dr. Feit testified that he would have expected Ethicon to inform him of the high number of reported complications associated with

SUI repairs received by the FDA between January 1, 2008 and December 31, 2010. (Id. at 63:6-23; 64:4-13; 84:2-9).

Within one year of implantation, Plaintiff began experiencing recurrent UTIs. In addition to UTIs, Plaintiff also reported she could not urinate after sexual intercourse and became bloated due to being unable to urinate. Between 2005 and 2009, Plaintiff was seen by healthcare providers on numerous occasions for follow-up regarding her recurrent UTIs and symptoms of urgency, frequency, dysuria and pain. In February 2015, Plaintiff underwent surgery to remove the TVT. The surgery was performed by Dr. Dionysios Veronikis in St. Louis, Missouri.

Plaintiff's general and case-specific expert Bruce Rosenzweig, M.D., opines, among other things, that Plaintiff's injuries were directly caused by the implantation of Ethicon's TVT Retropubic System. (Rule 26 Case Specific Expert Report of Bruce Rosenzweig, M.D. ("Rosenzweig Report), Doc. No. 45-4 at 3-4). Dr. Rosenzweig also opines that Ethicon's warnings about known risks were inadequate because Ethicon omitted information or minimized the actual risks of the TVT. (Id. at 21, 26-27).

III. Motion to exclude expert

Before addressing Ethicon's motion for summary judgment, the Court must address Ethicon's motion to exclude certain case-specific opinions and testimony of Dr. Rosenzweig. Dr. Rosenzweig is a urogynecologist who has performed over 1000 pelvic floor surgical procedures and over 350 surgeries dealing with complications related to synthetic mesh, including the removal of Ethicon Synthetic midurethral sling systems. (Id. at 2).

Dr. Rosenzweig provided a case-specific expert report in which he reviewed and outlined Plaintiff's medical history relating to the implantation of the Ethicon TVT Retropubic System device. (Id. at 5-19). He opines that Plaintiff's TVT caused her injuries, including "mesh

cording, a revision procedure, recurrent UTIs, vaginal pain, urge incontinence, frequency, urinary retention, nocturia, dysuria, voiding dysfunction, pelvic pressure, sexual cystitis, urethritis, urinary hesitancy, urethral stenosis, and stricture of urethral meatus.” (Id. at 19).

Dr. Rosenzweig also opines that: (1) Ethicon’s mesh, used in the TTV devices, is not suitable as a permanent prosthetic implant for SUI (id. at 20-21); (2) Ethicon knew the TTV was not appropriate for use but “failed to modify/change the meshes” (id.); (3) Ethicon’s “warnings and disclosures of adverse events in their [IFU] for this device ha[ve] been inadequate based on the adverse reactions and risks associated with it that have been known to Ethicon … from the time this device was first sold and marketed” (id. at 21-22); (4) that safer “alternative designs” and “reasonably feasible alternatives” existed for Plaintiff that were capable of preventing her injuries (id. at 22, 24-25); (4) Ethicon “failed to use reasonable care to provide adequate warnings” and “failed to act as reasonable and prudent medical device manufacturers by manufacturing and selling these polypropylene mesh products[;]” (id. at 4, 25); and (5) Plaintiff’s implanting physician, Dr. Feit, was not able to fully consent on her behalf because surgeons rely on the IFUs and Ethicon failed to include certain information in the TTV IFU (id. at 22, 26).

Ethicon seeks to exclude certain case-specific opinions and testimony of Dr. Rosenzweig, specifically: (1) opinions that amount to opinions regarding Ethicon’s state-of-mind, corporate conduct and marketing; (2) opinions containing legal conclusions, standards and terms of art; (3) opinions regarding informed consent; (4) opinions regarding allegedly safer alternatives for the treatment of SUI and pelvic organ prolapse; and (5) opinions not contained in his Case-Specific Report. (Doc. No. 42 at 1).

In her response, Plaintiff argues, among other things, that Ethicon is improperly challenging several of Dr. Rosenzweig's general opinions in the context of its motion to exclude case-specific opinions. Judge Goodwin has previously ruled in the Ethicon MDL, and in a related MDL, that Dr. Rosenzweig is qualified to testify as to the general causation issues related to TVT. See In re Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation, 2014 WL 186872, at *20 (S.D. W.Va. Jan. 15, 2014); In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation, 2018 WL 514753, at *3 (S.D. Va. Jan 23, 2018). However, the MDL court reserved ruling on Ethicon's objections to Dr. Rosenzweig's general opinions regarding, *inter alia*, safer alternative designs and the adequacy of product warnings. (Doc. No. 88 at 17-18). Accordingly, these objections necessitate a ruling by this Court.

A. Legal standard

The admission of expert testimony in federal court is governed by Federal Rule of Evidence 702. A district court acts as a “gatekeeper” when screening expert testimony for relevance and reliability. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 590-93 (1993); Russell v. Whirlpool Corp., 702 F.3d 450, 456 (8th Cir. 2012). To satisfy the reliability requirement, the party offering the expert testimony “must show by a preponderance of the evidence both that the expert is qualified to render the opinion and that the methodology underlying his conclusions is scientifically valid.” Barrett v. Rhodia, Inc., 606 F.3d 975, 980 (8th Cir. 2010) (quoting Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 757 (8th Cir. 2006)). To satisfy the relevance requirement, the proponent must show that the expert’s reasoning or methodology was applied properly to the facts at issue. Id.

The Court in Daubert emphasized that the inquiry required by FRE 702 is intended to be flexible. 509 U.S. at 594. The Daubert analysis was extended to all expert testimony, as opposed

to only “scientific” testimony. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 135, 147 (1999). Due to the liberalization of expert testimony admission standards signaled by Daubert and its progeny, and the codification of this trend by FRE 702, the Eighth Circuit has held that expert testimony should be liberally admitted. Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 562 (8th Cir. 2014) (citing United States v. Finch, 630 F.3d 1057, 1062 (8th Cir. 2011) (doubts about usefulness of expert testimony are resolved in favor of admissibility)); Robinson v. GEICO Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (expert testimony should be admitted if it advances the trier of fact’s understanding “to any degree”); Lauzon v. Senco Prod., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (FRE 702 “clearly is one of admissibility rather than exclusion”) (quotations omitted). As long as the expert testimony rests upon “good grounds, based on what is known,” it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded at the outset. Id. (citing Daubert, 509 U.S. at 596). Exclusion of an expert opinion is proper “only if it is so fundamentally unsupported that it can offer no assistance to the jury.” Wood v. Minnesota Mining & Mfg. Co., 112 F.3d 306, 309 (8th Cir. 1997) (citation and quotation marks omitted).

B. Discussion

The Court notes that Dr. Rosenzweig is one of several experts in this case who have testified in other related actions, including the MDL. Other plaintiffs from this MDL have proffered Dr. Rosenzweig for precisely the same opinions, and defendant-manufacturers, including Ethicon, have moved to exclude for similar reasons. Yet courts have denied the motions. See, e.g., Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691 (S.D.W. Va. 2014); Dorgan v. Ethicon, Inc., No. 4:20-00529-CV-RK, 2020 WL 5367062 (W.D. Mo. Sept. 8, 2020); Hosbrook v. Ethicon, Inc., No. 3:20-cv-88, 2020 WL 5214644 (S.D. Ohio Sept. 1, 2020); Russell v.

Ethicon, Inc., No. 4:20-cv-00752-ACA, 2020 WL 4732106 (N.D. Ala. August 14, 2020); Chrastecky v. C.R. Bard, Inc., No. A-19-CV-1240-LY-SH, 2020 WL 748182 (W.D. Tex. February 14, 2020); Armstead v. Coloplast Corp., No. 1:19-CV-1000, 2020 WL 353576 (M.D. N.C. Jan. 21, 2020). The Court has looked to many of these opinions for guidance.

Ethicon's state of mind or corporate knowledge

Ethicon first objects to Dr. Rosenzweig's opinions concerning its conduct, knowledge, and state of mind, specifically, that Ethicon knew the TVT was "not appropriate for use but ... failed to modify/change the meshes[;]" (Rosenzweig Report at 20); that the product IFU is inadequate because Ethicon omitted adverse reactions "that have been known to Ethicon ... from the time this device was first sold and marketed" and "despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold" (*id.* at 21, 26); that Ethicon was "unwilling to change the devices because of [its] economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon ... has put profits before patient safety" (*id.* at 20); and that Ethicon failed to include certain information in "marketing documents" (*id.* at 21).

The Court agrees that experts may not testify about what other parties did or did not know. See, e.g., In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). However, to the extent Ethicon seeks to exclude Dr. Rosenzweig's testimony about factual issues or the knowledge of the medical community in general, the Court disagrees. Expert witnesses may properly offer opinions on these topics. Therefore, Ethicon's motion is granted to the extent that it seeks to exclude evidence regarding Ethicon's knowledge, state of mind, or other matters

related to corporate conduct, and denied to the extent it seeks to exclude opinions about factual issues or the knowledge of the medical community in general. In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2326, 2018 WL 2426155, at *2 (S.D.W. Va. May 29, 2018).

Opinions containing legal conclusions, standards and terms of art

Ethicon seeks to exclude certain opinions expressed by Dr. Rosenzweig that it believes state a legal standard or draw a legal conclusion. Specifically, Ethicon objects to those opinions of Dr. Rosenzweig asserting that Ethicon “failed to act as a reasonable and prudent medical device manufacturer[]” (Rosenzweig Report at 4); that Ethicon’s “warnings and disclosures of adverse events” in its IFU for TVT have “been inadequate” (*id.* at 21); that Ethicon failed to use reasonable care to provide adequate warnings” (*id.* at 15); and that “[a]s a result of the defects in this mesh . . .”) (*id.* at 22). Plaintiff responds that under FRE 704, an opinion is not objectionable simply because it embraces an ultimate issue, and that Dr. Rosenzweig may opine on product risks, adequacy of warnings, and the knowledge of the medical community.

Dr. Rosenzweig’s opinions however, go beyond the efficacy of the TVT’s product design or the adequacy of the warnings. “[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” United States v. McIver, 470 F.3d 550, 562 (4th Cir. 2006). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” See Perez v. Townsend Eng’g Co., 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Throughout the MDLs and related actions, courts have prohibited the parties from using experts to usurp the jury’s fact-finding function by allowing testimony of this type. See In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2187, 2018 WL 4212409, at *3 (S.D.W. Va. Sept. 4, 2018); In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig., 2018 WL

2426155, at *3. Thus, to the extent that Dr. Rosenzweig's opinions constitute legal conclusions, those opinions are excluded.

Opinions regarding informed consent

Here, Ethicon argues that by opining that Dr. Feit could not obtain informed consent from Plaintiff because of Ethicon's allegedly inadequate warnings, Dr. Rosenzweig is effectively opining as to Dr. Feit's personal knowledge at the time he was making the prescribing decision, which is not helpful to the jury. In addition, Ethicon argues that the adequacy of the informed consent process is not at issue in this case; rather, under the learned intermediary doctrine, the only relevant issue is whether the warnings provided by Ethicon to the implanting physician were adequate.

In Dorgan, the court found these arguments without merit:

First, while the opinions about the sufficiency of warnings are inherently intertwined to the issue of whether Ms. Dorgan could give informed consent, they remain two distinct issues. Plaintiffs must prove causation. In this case, regarding warnings, Plaintiffs will have to prove that a sufficient warning(s) (either to the medical providers or patient), would have altered Ms. Dorgan's behavior. In Missouri, plaintiffs are entitled to the presumption that, if an adequate warning had been given, they would have heeded it. Such an issue touches on not only the adequacy of the warnings, but their effect on patient behavior via an informed consent process. Second, Dr. Rosenzweig will not testify to any of Dr. Austin's personal knowledge. Rather, Dr. Rosenzweig opines as to the sufficiency of warnings given to surgeons like Dr. Austin and how the lack of warnings affected the informed consent process. Therefore, Defendants' motion will be denied on this point.

2020 WL 5367062, at *3 (internal citations omitted). The Court will likewise deny Ethicon's motion on this basis.

Opinions regarding safer alternatives

Ethicon argues Dr. Rosenzweig's opinions regarding safer alternatives are unreliable and irrelevant. Again, this identical argument was rejected in Dorgan:

As to the relevance argument, whether a safer alternative exists and whether it would have reduced or eliminated the risk of injury goes to the heart of causation and damages ... As to reliability, Defendants argue there is no basis for Dr. Rosenzweig's opinion that had Ms. Dorgan used alternative designs she would not have suffered her injuries. Dr. Rosenzweig's opinion is based on his experience with the alternatives proposed in his report and his opinion that Ms. Dorgan's injuries were caused by the specific design flaws of the TVT. As Dr. Rosenzweig explains, every other alternative uses less or no polypropylene. Finally, Dr. Rosenzweig states these opinions to a reasonable degree of medical certainty, not absolute certainty. Merely because there may be a chance the injuries would occur using an alternative product does not warrant the full exclusion of the opinions.

2020 WL 5367062, at *3 (internal citations omitted). The Court finds Dr. Rosenzweig's opinions are sufficiently reliable and will, therefore, deny Ethicon's motion on this basis. To the extent Ethicon disagrees with these opinions, they are subject to cross-examination.

Opinions not contained in case-specific report

Lastly, citing Ridgley v. Ethicon, Inc., No. 2:12-cv-01311, 2017 WL 532124 (S.D. W. Va. Feb. 8, 2017), Ethicon argues that Dr. Rosenzweig should be precluded from opining that Plaintiff suffered dyspareunia as a result of the TVT because this opinion was not included in his expert report, and thus lacks a sufficiently reliable foundation. Plaintiff responds that Dr. Rosenzweig's opinion was timely disclosed (see Rosenzweig Report at 23) ("The mesh revision procedures were indicated due to complaints of UTIs, pelvic pain, urinary retention, and *dyspareunia....*"), but that it was merely a typo or mistake for not listing it on certain pages. (Doc. No. 47 at 17). In further response, Plaintiff asserts that Dr. Rosenzweig's opinion is reliable because it incorporates Dr. Veronikis' pre- and post-operative diagnoses of *dyspareunia*, mesh problems, and urinary retention and his opinion that Plaintiff's dyspareunia was caused by the cording of the TVT mesh. (Id. at 17-18).

Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i).

Therefore, an expert's testimony generally is limited to his or her report produced in accordance with Rule 26 (a)(2)(B), and to explanations that are reasonably necessary to explain the opinions in his report. Chrastecky, 2020 WL 748182, *8. Dr. Rosenzweig's deposition opinion that Plaintiff's dyspareunia was caused by the TVT is unsupported by a differential diagnosis and thus lacks sufficient foundation to be admissible. Id.; see also Ridgley, 2017 WL 532124, at *3. Accordingly, Ethicon's motion will be granted on this basis.

IV. Motion for summary judgment

As a threshold matter, Plaintiff does not oppose summary judgment as to Count II (strict liability – manufacturing defect); Count XI (breach of express warranty); and Count XIII (violation of consumer protection laws). (Doc. No. 45 at 13, 18). Accordingly, Ethicon's motion is granted as to these counts, all of which are dismissed with prejudice.

A. Legal standard

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The Court must view the evidence and inferences that "may be reasonably drawn from the evidence in the light most favorable to the nonmoving party." Enter. Bank v. Magna Bank of Mo., 92 F.3d 743, 747 (8th Cir. 1996). The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). A party opposing a properly supported motion for summary judgment may not rest on mere allegations or denials, but must set forth specific facts in the record showing there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986).

In support of summary judgment on Plaintiff's remaining claims, Ethicon argues they are all barred by Missouri's five-year statute of limitations for personal injury actions. Mo. Rev. Stat.

§ 516.120(4).³ Alternatively, Ethicon argues the following claims should be dismissed for failure to state a claim as a matter of law: negligence (to the extent based on negligent failure to warn or negligent manufacturing defect) (Count I); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); common law fraud (Count VI); fraudulent concealment (Count VIII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of implied warranty (Count XII); gross negligence (Count XIV); and unjust enrichment (Count XV).

B. Discussion⁴

Statute of limitations

Where a motion for summary judgment raises the issue of statute of limitations and involves the determination of when a cause of action accrued, “summary judgment cannot be granted unless the evidence is so clear that there is no genuine factual issue and the determinations can be made as a matter of law.” May v. AC & S, Inc., 812 F. Supp. 934, 938 (E.D. Mo. 1993) (quoting Hildebrandt v. Allied Corp., 839 F.2d 396, 399 (8th Cir. 1987)).

Under Missouri law, a claim accrues not when the wrong is done, “but when the damage resulting therefrom is sustained and is capable of ascertainment.” Mo. Rev. Stat. § 516.100. The Missouri Supreme Court has defined “capable of ascertainment” as when “the evidence [is] such to place a reasonably prudent person on notice of a potentially actionable injury.” Levitt v. Merck & Co., Inc., 914 F.3d 1169, 1171–72 (8th Cir. 2019) (quoting Powel v. Chaminade Coll. Preparatory, Inc., 197 S.W.3d 576, 582 (Mo. 2006) (emphasis removed)). This “objective” test is

³ The parties do not dispute that Missouri law governs their dispute or that the statute of limitations applicable to Plaintiff’s claims is five years. Mo. Rev. Stat. § 516.120(4).

⁴ Given the thousands of related multidistrict-litigation actions across the country arising from mesh-sling implants, the Court has looked to dozens of district court and circuit court opinions on nearly identical issues raised for guidance in addressing Ethicon’s motion.

from the standpoint of a “reasonable person in [plaintiff’s] situation.” Id. (quoting Powell, 197 S.W.3d at 584, 586). Both the “character of the condition ... and its cause” must be capable of ascertainment. Id. (quoting Elmore v. Owens-Illinois, Inc., 673 S.W.2d 434, 436 (Mo. 1984)). If, as here, a claim is based on a “physical ailment, it is sustained and capable of ascertainment, at the latest when (i) it is diagnosed, and (ii) a theory as to its cause is ascertainable.” Buttice v. G.D. Searle & Co., 938 F. Supp. 561, 566–67 (E.D. Mo. 1996).

Ethicon argues that the undisputed facts establish that Plaintiff’s injuries were first sustained and capable of ascertainment when she was diagnosed with recurrent UTIs in 2005, particularly in light of the medical literature from 2000 advising surgeons that UTIs are a potential complication that can occur following implantation of TVT, and no later than 2008, when the FDA issued a public health notification warning that TVT implants can cause complications such as pain, infections, and urinary problems. Plaintiff responds that her claims were not capable of ascertainment at that time because none of her treating physicians were relating the TVT to her symptoms, and that a definite causal link was not established until she saw Dr. Veronikis in 2015. Plaintiff also asserts entitlement to tolling based on fraudulent concealment, alleging a “conspiracy of misinformation and misdeeds regarding [Ethicon’s] TVT product for years...” (Doc. No. 45 at 9).

Like other federal district courts have found in similar cases, this Court finds that questions of fact remain in dispute concerning when Plaintiff should have known her injuries were related to the TVT. When viewing the record in the light most favorable to Plaintiff, and drawing all legitimate inferences in her favor, a jury could reasonably determine that her injuries were not apparent or reasonably apparent to her more than five years before she filed her complaint, and thus not time barred. The Court notes that under Missouri law as predicted by the

Eighth Circuit Court of Appeals, mere knowledge in the medical community of a possible link does not as a matter of law place a reasonably prudent person on notice of a potentially actionable injury. See Levitt v. Merck & Co., Inc., 914 F.3d 1169, 1174 (8th Cir. 2019). Accordingly, Ethicon's motion based on Missouri's statute of limitations will be denied. See, e.g., Cooper v. Ethicon, Inc., No. 2:12-CV-02532, 2017 WL 2624547, at *2 (S.D.W. Va. June 16, 2017); Williams v. Ethicon, Inc., No. 2:12-CV-00511, 2017 WL 107976, at *4 (S.D.W. Va. Jan. 10, 2017); McBrayer v. Ethicon, Inc., No. 2:12-CV-00779, 2017 WL 73934 (S.D.W. Va. Jan. 6, 2017); In re Bos. Sci. Corp., Pelvic Repair Sys. Prod. Liab. Litig., No. 2:13-CV-15591, 2015 WL 1276714, at *4 (S.D.W. Va. Mar. 19, 2015).

Manufacturing defect claims (Counts I, X, XIV)

A manufacturing defect occurs when something goes wrong in the manufacturing process and the product deviates from its intended condition. Gillan v. Wright Med. Tech. Inc., 396 F. Supp. 3d 844, 848 (E.D. Mo. 2019) (citation omitted). In a manufacturing defect case, the product is evaluated against the manufacturer's own standards and compared to similar products. Id. Ethicon argues that Counts I (negligence), X (negligent infliction of emotional distress) and XIV (gross negligence) should be dismissed because there is no evidence the TTVT deviated from its intended specifications. (Doc. No. 40 at 10). As noted above, Plaintiff has conceded her separate claim for manufacturing defect in Count II, but continues to maintain her claims for general negligence (Count I) and negligent infliction of emotional distress (Count X). (Doc. No. 45 at 13-14). The Court will, therefore, dismiss Counts I and X as to manufacturing defects. See Dorgan v. Ethicon, Inc., No. 4:20-00529-CV-RK, 2020 WL 5372134, at *2 (W.D. Mo. Sept. 8, 2020). As to claims of general negligence, Count X will be dismissed as discussed below.

Further, Ethicon's motion will be granted as to Count XIV (gross negligence) because Missouri courts do not recognize degrees of negligence. Decormier v. Harley-Davidson Motor Company Group, Inc., 446 S.W.3d 668, 671 (Mo. 2014) (en banc) (emphasis added). "Indeed, the Missouri Supreme Court has stated 'the plaintiff gains nothing by branding the negligence "gross"' because Missouri has consistently refused to recognize differing degrees of negligence."

Boyer v. Tilzer, 831 S.W.2d 695, 697 (Mo. Ct. App. 1992) (quoting Sherrill v. Wilson, 653 S.W.2d 661, 664 (Mo. Ct. App. 1983) (en banc)). Because gross negligence is not a claim recognized under Missouri law, Count XIV will be dismissed with prejudice.

Failure to warn claims (Counts I, III)

To establish a failure to warn claim under Missouri law, a plaintiff must show: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning. Moore v. Ford Motor Co., 332 S.W.3d 749, 756 (Mo. banc 2011). While a plaintiff must show a product was unreasonably dangerous, Missouri law does not hold "that a finding of a product defect [is] a necessary predicate to a failure to warn action." Id. at 757.

Ethicon argues that Plaintiff has failed to establish causation under the learned intermediary doctrine. (Doc. No. 40 at 11-12). The learned intermediary doctrine provides that a manufacturer of prescription drugs or medical devices has a duty to warn a physician of the risks involved with its product. The physician then acts as a "learned intermediary" between the manufacturer and the patient so that any warning given to the physician is deemed a warning to

the patient. Redd v. DePuy Orthopaedics, Inc., 48 F. Supp. 3d 1261, 1270–71 (E.D. Mo. 2014) (citing Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999)).

Thus, to state a claim for failure to warn in a prescription medical device case in Missouri, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Brinkley v. Pfizer, Inc., 772 F.3d 1133, 1138–39 (8th Cir. 2014). Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product. Id.

Ethicon argues that no such showing has been made here. In so doing, Ethicon relies on a portion of Dr. Feit's deposition testimony. In response to a question about whether his decision to prescribe TTV for Plaintiff in 2003 would have been affected if the IFU had included "all those risks we just talked about, chronic pain and so forth," Dr. Feit answered "no." (Feit Depo. at 23:1-13; 90:11-91:3). However, Dr. Feit also testified it would have been important to him to know (i) whether the TTV mesh exhibited an increased risk of erosion, extrusion, and contraction (id. at 66:8-14; 76:25-77:17); (ii) whether the TTV mesh is brittle, causing particle loss (id. at 79:1-22); (iii) whether the TTV could curl and rope, increasing the potential for retention (id. at 81:23-82:13); and (iv) whether the TTV causes chronic local irritation at the wound site and a chronic foreign body response (id. at 84:15-25). Plaintiff also presents evidence that Ethicon failed to disclose to consumers (physicians and patients alike) the risks and complications associated with TTV despite its knowledge that TTV posed unreasonable risks to

them. (See Rosenzweig Report). This evidence, when viewed in the light most favorable to Plaintiff, supports a reasonable inference that Dr. Feit would have discussed these risks with her had Ethicon properly warned him about their existence in the IFUs or otherwise. Thus, on this record, there are genuine issues of material fact as to causation that preclude summary judgment on Plaintiff's failure to warn claims. See Aldridge v. Ethicon, Inc., No. 20-0039-WS-B, 2020 WL 1308335, *4 (S.D. Ala. Mar. 19, 2020); Dorgan v. Ethicon, Inc., No. 4:20-00529-CV-RK, 2020 WL 5372134, at *3 (W.D. Mo. Sept. 8, 2020). Ethicon's motion will be denied on this basis.

Strict liability – defective product claim (Count IV)

Citing Davis v. Dunham's Athleisure Corp., 362 F. Supp. 3d 651, 658 (E.D. Mo. 2019), Ethicon argues this claim fails as a matter of law because in Missouri, strict liability can only be based on a design or manufacturing defect, or a failure to warn. (Doc. No. 40 at 13). In response, Plaintiff cites Smith v. Brown & Williamson Tobacco Corp., 275 S.W.3d 748, 791 (Mo. Ct. App. 2008), which held that “[a] manufacturer is liable under a strict liability product defect claim if the product was in an unreasonably dangerous defective condition when put to a reasonably anticipated use, and the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.” Id. (citation, quotation marks, and emphasis omitted).

However, the elements for strict liability defective product are identical to strict liability defective design. Linegar v. Armour of Am., Inc., 909 F.2d 1150, 1152 (8th Cir. 1990) (listing the same elements for strict liability design defect as the ones listed above). Because the cause of action for strict liability defective product (Count IV) is the same as strict liability design defect (Count V), the Court will grant Ethicon's motion on this point and dismiss Count IV with prejudice. See Dorgan, 2020 WL 5372134, at *2.

Fraud and warranty claims (Counts VI, VII, VIII, IX, XII)

Ethicon argues that Plaintiff's fraud and warranty claims should be dismissed as duplicative of her failure to warn claims because the gravamen of those allegations is that Ethicon failed to adequately disclose the risks of TTVT. (Doc. No. 40 at 13-14). This argument was recently rejected in Dorgan:

Defendants' arguments are without merit. Defendants' argument revolves around the learned intermediary doctrine. The learned intermediary doctrine is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products. In Missouri, the doctrine applies only if the manufacturer satisfies its duty to properly warn the doctor of the dangers involved. Here, Plaintiffs provide sufficient evidence that Defendants' warnings, even to doctors, were insufficient. Thus, there exists a genuine issue of material fact, the applicability of the learned intermediary doctrine is in question, and summary judgment is not warranted on this point.

2020 WL 5372134, at *3 (internal quotation marks, citations omitted).

Alternatively, Ethicon argues that Plaintiff's claims for common law fraud (Count VI) and negligent misrepresentation (Count IX) fail for lack of proof that either Plaintiff or Dr. Feit relied upon any representation from Ethicon in proceeding with her TTVT implant. (Doc. No. 40 at 14). Again, Plaintiff's evidence is that Ethicon fraudulently misrepresented or suppressed known risks about the TTVT mesh in the warnings given to Dr. Feit, the learned intermediary. As discussed above, the record in the light most favorable to Plaintiff supports a reasonable inference that Dr. Feit reasonably relied on the accuracy and completeness of those warnings, and that Plaintiff reasonably relied on Dr. Feit. Aldridge, 2020 WL 1308335 at *5. Accordingly, Ethicon's motion for summary judgment will be denied as to Counts VI, VII, VIII, IX, XII on these grounds. However, Counts VII and VIII will be dismissed for other reasons as set forth below.

Fraudulent concealment (Count VII)

Under Missouri law, fraudulent concealment is not an independent cause of action. See, e.g., Nestlé Purina Petcare Co. v. Blue Buffalo Co., 181 F. Supp. 3d 618, 640 (E.D. Mo. 2016) (“Missouri courts have not recognized a separate claim of fraudulent concealment.”). Instead, “in cases where misrepresentation is alleged to have occurred by nondisclosure, ‘a party’s silence in the face of a legal duty to speak replaces the first element [of a fraudulent misrepresentation claim]: the existence of a representation.’ ” Id. (quoting Hess v. Chase Manhattan Bank, USA, 220 S.W.3d 758, 765 (Mo. 2007)). Thus, Plaintiff cannot maintain an independent claim for fraudulent concealment and Ethicon’s motion for summary judgment will be granted on this point.

Constructive fraud (Count VIII)

Ethicon argues that Plaintiff’s claim fails because she had no fiduciary or confidential relationship with Ethicon. (Doc. No. 40 at 16). Under Missouri law, “[c]ourts have equated constructive fraud with the breach or violation of a fiduciary, or confidential, relationship.” Fix v. Fix, 847 S.W.2d 762, 765 (Mo. 1993). “One of the key elements of a fiduciary relationship ... is the fiduciary’s control of the supervised party’s property.” Arnold v. Erkmann, 934 S.W.2d 621, 629 (Mo. Ct. App. 1996); accord Day v. Hupp, 528 S.W.3d 400, 416 (Mo. Ct. App. 2017) (“A confidential relationship exists when one person relies on and trusts another with management of her property and attendance to her affairs, thereby creating some degree of fiduciary obligation.”). A manufacturer’s superior knowledge of a product does not satisfy this requirement. See Simply Thick, LLC v. Thermo Pac, LLC, No. 4:13-CV-1036 CAS, 2014 WL 3543403, at *6 (E.D. Mo. July 17, 2014). Because Plaintiff has presented no evidence to support the existence of a fiduciary or confidential relationship with Ethicon, her constructive fraud claim fails. Ethicon’s motion for summary judgment will be granted on this point.

Breach of implied warranty (Count XII)

To recover for breach of implied warranty of merchantability under Missouri law, “a plaintiff must prove: (1) that a merchant sold goods, (2) which were not ‘merchantable’ at the time of the sale, (3) injury and damages to the plaintiff or his property (4) which were caused proximately or in fact by the defective nature of the goods, and (5) notice to the seller of the injury.” Johnsen v. Honeywell Int'l Inc., No. 4:14CV594 RLW, 2015 WL 631361, at *5 (E.D. Mo. Feb. 12, 2015) (citing Ragland Mills, Inc. v. General Motors, Corp., 763 S.W.2d 357, 360 (Mo. Ct. App. 1989)). Ethicon argues this claim fails because there is no evidence that Plaintiff provided the required pre-suit notice. See Mo. Rev. Stat. 400.2-607(3)(a) (Failure to provide timely notice bars the plaintiff “from any remedy.”).

Plaintiff’s reliance on Tyree v. Bos. Sci. Corp., No. 2:12-CV-08633, 2014 WL 5320518, at *5 (S.D. W.Va. Oct. 17, 2014), construing West Virginia’s Implied Warranty of Merchantability law, is misplaced. In Tyree, the issue concerned the sufficiency of the evidence that the Obtryx was fit for its ordinary purpose, i.e., treating SUI. Plaintiff has not, however addressed Ethicon’s argument that there is nothing in the record to show she gave Ethicon timely notice of breach. The failure to oppose a basis for summary judgment constitutes waiver of that argument. Satcher v. Univ. of Arkansas at Pine Bluff Bd. of Trustees, 558 F.3d 731, 735 (8th Cir. 2009). Thus, Ethicon’s motion for summary judgment will be granted as to Plaintiff’s claim for breach of implied warranty of merchantability. To the extent Plaintiff’s claim is based on the implied warranty of fitness for a particular purpose, Ethicon’s motion will likewise be granted, as Plaintiff has not opposed Ethicon’s motion on this issue. Id.

Negligent infliction of emotional distress (Count X)

To state a claim for negligent infliction of emotional distress (“NEID”), a plaintiff must plead the general elements of negligence, i.e., “a legal duty of the defendant to protect the plaintiff from injury;” a breach of that duty; proximate cause; and injury – as well as two additional elements – “that the defendant should have realized that his conduct involved an unreasonable risk of causing distress” and “that the emotional distress or mental injury must be medically diagnosable and must be of sufficient severity so as to be medically significant.” Couzens v. Donohue, 854 F.3d 508, 518 (8th Cir. 2017) (quoting Thornburg v. Fed. Express Corp., 62 S.W.3d 421, 427 (Mo. Ct. App. 2001)). Ethicon argues this claim fails for lack of proof, much less any allegation, of severe emotional harm. Plaintiff’s causation expert, Dr. Rosenzweig, has not identified any mental injury caused by or related to the TTVT; Plaintiff has not identified mental or psychological harm as an injury caused by the TTVT, and denies being diagnosed with or treated for any mental health condition since her TTVT implantation. Because Plaintiff has not addressed Ethicon’s argument in her response, Ethicon’s motion for summary judgment will be granted as to Plaintiff’s NEID claim. See Satcher, 558 F.3d at 735 (failure to oppose a basis for summary judgment constitutes waiver of that argument).

Unjust Enrichment (Count XV)

Finally, Ethicon argues that Plaintiff’s unjust enrichment claim fails. “To establish the elements of an unjust enrichment claim, the plaintiff must prove that (1) he conferred a benefit on the defendant; (2) the defendant appreciated the benefit; and (3) the defendant accepted and retained the benefit under inequitable and/or unjust circumstances.” Howard v. Turnbull, 316 S.W.3d 431, 436 (Mo. Ct. App. 2010). The retention of a benefit is considered unjust “when the benefits were ‘conferred (a) in misreliance on a right or duty; or (b) through dutiful intervention in another’s affairs; or (c) under constraint.’” Id. (quoting Graves v. Berkowitz, 15 S.W.3d 59, 62

(Mo. Ct. App. 2000). When the plaintiff receives what he intended to obtain, there is no unjust enrichment. Id. (citation omitted). Ethicon contends that summary judgment is warranted because Plaintiff did not confer a benefit directly on Ethicon; any retention of benefits by Ethicon was not unjust; and Plaintiff actually received the product they intended to obtain. (Doc. No. 40 at 19).

Plaintiff has not opposed Ethicon's motion with respect to this claim in her response. Again, when the nonmoving party does not mention a claim in response to a motion for summary judgment, the claim is deemed abandoned. Satcher, 558 F.3d at 735. Ethicon's motion for summary judgment will be granted on this point.

V. Conclusion

Accordingly,

IT IS HEREBY ORDERED that Defendants Ethicon, Inc. and Johnson & Johnson's Motion for Summary Judgment [39] is **GRANTED in part** and **DENIED in part** as follows:

1. Ethicon's motion for summary judgment as to Counts II (strict liability – manufacturing defect), XI (breach of express warranty), XIII (violation of consumer protection laws), and XIV (gross negligence) is **GRANTED** and Counts II, XI, XIII and XIV are dismissed;
2. Ethicon's motion as to Counts I (negligence) and X (negligent infliction of emotional distress) is **GRANTED** as to claims of manufacturing defect. To the extent Plaintiff maintains Counts I and X under general negligence theories, Ethicon's motion is **GRANTED** as to Count X and Count X is dismissed;
3. Ethicon's motion as to Count IV (strict liability – defective product) is **GRANTED** and Count IV is dismissed;
4. Ethicon's motion as to Count VI (common law fraud) is **DENIED**;
5. Ethicon's motion as to Counts VII (fraudulent concealment) and VIII (constructive fraud) is **GRANTED**; and Counts VII and VIII are dismissed;

6. Ethicon's motion as to Count IX (negligent misrepresentation) is **DENIED**;
7. Ethicon's motion as to Count X (negligent infliction of emotional distress) is **GRANTED** and Count X is dismissed;
8. Ethicon's motion as to Count XII (breach of implied warranty) is **GRANTED** and Counts XII is dismissed; and
9. Ethicon's motion as to Count XV (unjust enrichment) is **GRANTED** and Count XV is dismissed.

Thus, the remaining claims are:

Count I - general negligence
Count III - strict liability failure to warn
Count V - strict liability design defect
Count VI - fraud
Count IX - negligent misrepresentation
Count XVII - punitive damages
Count XVIII - discovery rule and equitable tolling

IT IS FURTHER ORDERED that Plaintiff's Motion to Limit the Case-Specific Opinions and Testimony of Bruce Rosenzweig, M.D. [41] is **GRANTED in part** and **DENIED in part** in accordance with the rulings herein.

Dated this 30th day of September, 2020.



John A. Ross
JOHN A. ROSS
UNITED STATES DISTRICT JUDGE